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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/043,356

01/11/2002

Jerome Lapointe

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7590

05/29/2008

CYTYC CORPORATION

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MARLBOROUGH, MA 01752

EXAMINER

STARKS, WILBERT L

ART UNIT

PAPER NUMBER

2129

MAIL DATE

DELIVERY MODE

05/29/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/043,356	<b>Applicant(s)</b> LAPOINTE ET AL.	
	<b>Examiner</b> Wilbert L. Starks, Jr.	<b>Art Unit</b> 2129	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 February 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                      |                                                                   |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____                                                          | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Claim Rejections - 35 U.S.C. §102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-6 are rejected under 35 U.S.C. §102(b) as being anticipated by Hutcheson, et al (U.S. Patent Number 5,465,308 A; dated 07 NOV 1995; class 382; subclass 159). Specifically:

#### **Claim 1**

Claim 1's "A computer system, comprising a neural network or plurality thereof trained for diagnosing endometriosis." is anticipated by Hutcheson, et al, column 28, lines 61-67 and column 29, lines 1-16. The claimed neural network is anticipated by the prior art's "supervised learning." The claimed endometriosis diagnostic signals are anticipated by the prior art's "medical diagnostic signals."

#### **Claim 2**

Claim 2's "querying and examining the patient to assess the answers to at least three of the following questions: past history of endometriosis, number of births, dysmenorrhea, age, pelvic pain, history of pelvic surgery, smoking and if yes, the

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number of packs/day, medication history, number of pregnancies, number of abortions, abnormal PAP smear/dysplasia, pregnancy hyperplasia, genital warts and diabetes; and" is anticipated by Hutcheson, et al, column 28, lines 61-67 and column 29, lines 1-16. The claimed diagnostic signals are anticipated by the prior art's "medical diagnostic signals."

Claim 2's "based upon the results of the answers determining whether the patient has endometriosis." is anticipated by Hutcheson, et al, column 28, lines 61-67 and column 29, lines 1-16. The claimed diagnostic signals are anticipated by the prior art's "medical diagnostic signals."

### **Claim 3**

Claim 3's "A computer system, comprising a neural network or plurality thereof trained for assessing the risk of delivery within a selected time period, wherein the time period is within seven or fourteen days of performing a biochemical test to measure fetal fibronectin in a sample from a pregnant subject or the time period is prior to thirty five weeks of gestation." is anticipated by Hutcheson, et al, column 28, lines 61-67 and column 29, lines 1-16. The claimed diagnostic signals are anticipated by the prior art's "medical diagnostic signals."

### **Claim 4**

Claim 4's "The system of claim 3, wherein the time period is within seven days of performing a biochemical test to measure fetal fibronectin." is anticipated by Hutcheson,

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et al, column 28, lines 61-67 and column 29, lines 1-16. The claimed diagnostic signals are anticipated by the prior art's "medical diagnostic signals."

#### **Claim 5**

Claim 5's "The system of claim 3, wherein the time period is within or fourteen days of performing a biochemical test to measure fetal fibronectin." is anticipated by Hutcheson, et al, column 28, lines 61-67 and column 29, lines 1-16. The claimed diagnostic signals are anticipated by the prior art's "medical diagnostic signals."

#### **Claim 6**

Claim 6's "The system of claim 3, wherein the time period is prior to thirty five weeks of gestation." is anticipated by Hutcheson, et al, column 28, lines 61-67 and column 29, lines 1-16. The claimed diagnostic signals are anticipated by the prior art's "medical diagnostic signals."

#### ***Response to Arguments***

Applicant's arguments filed 02/20/2008 have been fully considered but they are not persuasive. Specifically, Applicant argues:

#### **Argument 1**

Applicant argues that the prior art does not anticipate a neural network for diagnosing endometriosis. Applicant does not argue a structural difference in the

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invention. Applicant only argues a use to which the structure may be put. Endometriosis diagnosis is anticipated because the prior art may be applied to "...medical diagnostic signals such as EKG, EEG etc., and any other sensor signal." Applicant has not shown that endometriosis diagnostic data are not "medical diagnostic signals."

The "system" (i.e., "apparatus") claimed by Applicant is anticipated in all respects. Applicant presented no method claims. The structure of the claimed apparatus is anticipated by the prior art. Had Applicant claimed the method (including specific data acquisition steps), it is likely it would have been easy to find such method steps in other prior art and, therefore, such steps would have been obvious over the prior art. Such an issue is moot, however. Applicant claimed the apparatus and it is anticipated by the prior art. Therefore, Applicant's argument is not persuasive.

### **Argument 2**

Applicant argues that the prior art does not anticipate a neural network for diagnosing endometriosis.

The prior art discloses the use of "supervised learning techniques." Applicant did not claim that he was using a neural network that used unsupervised learning techniques. The most common neural networks (i.e., backpropagation neural networks) use supervised learning. Applicant has not shown that the claimed neural networks not "supervised learning systems."

The "system" (i.e., "apparatus") claimed by Applicant is anticipated in all respects.

Therefore, Applicant's argument is not persuasive.

### **Argument 3**

Applicant argues further that the prior art does not anticipate querying and examination of a patient. The prior art may be applied to "...medical diagnostic signals such as EKG, EEG etc., and any other sensor signal." Applicant has not shown that diagnostic data from "querying and examination of a patient" are not "medical diagnostic signals."

The "system" (i.e., "apparatus") claimed by Applicant is anticipated in all respects.

Therefore, Applicant's argument is not persuasive.

### **Argument 4**

Applicant argues further that the prior art does not anticipate a neural network for assessing the risk of delivery in a time period. The prior art may be applied to "...medical diagnostic signals such as EKG, EEG etc., and any other sensor signal." Applicant has not shown that data for "assessing the risk of delivery in a time period" are not "medical diagnostic signals."

The "system" (i.e., "apparatus") claimed by Applicant is anticipated in all respects.

Therefore, Applicant's argument is not persuasive.

### **Argument 5**

Applicant argues further that the prior art does not anticipate a time period within 7-14 days of performing a biochemical test to measure fetal fibronectin in a sample from a pregnant subject. The prior art may be applied to "...medical diagnostic signals such as EKG, EEG etc., and any other sensor signal." Applicant has not shown that data acquired within "a time period within 7-14 days of performing a biochemical test to measure fetal fibronectin in a sample from a pregnant subject" are not "medical diagnostic signals."

The "system" (i.e., "apparatus") claimed by Applicant is anticipated in all respects.

Therefore, Applicant's argument is not persuasive.

### **Argument 6**

Applicant argues further that the prior art is not enabling, therefore, cannot anticipate under §102. The prior art is an allowed patent. For purposes of examination, It is enabled. Applicant's fundamental premise is incorrect. Therefore, Applicant's argument is unpersuasive.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).



A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Wilbert L. Starks, Jr. whose telephone number is (571) 272-3691.

Alternatively, inquiries may be directed to the following:

**S. P. E. David Vincent** (571) 272-3080

**Official (FAX)** (571) 273-8300

/Wilbert L. Starks, Jr./

Primary Examiner, Art Unit 2129

WLS

26 MAY 2008

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